DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS **DESCRIBED IN 21 CFR 1271.10**

Ext.:

FEI: 3003103596

Reporting Official:

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/19/2023 Summary Report Print Date: 01/05/2024

Legal Name and Location:

Indianapolis, Indiana 46222

Phone: 317-685-0389

USA

Indiana Organ Procurement Organization dba Indiana Donor Network

3750 Guion Road

Sarah E Lee, Manager, Regulatory Compliance 3750 Guion Road Indianapolis, Indiana 46222

Phone: 317-222-3407 Ext. slee@indonornetwork.org

Satellite Recovery Establishment: No

Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only:

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

No

Matter M	Filone. 317-003-0309	LAU.										
Mariotic Membrane	Establishment Functions											
Blood Vessel	HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Proprietary Name(s)
Bone	Amniotic Membrane											
Cardiac Tissue N X	Blood Vessel		х	Х		Х			Х			
Carliage X<	Bone		Х	Х		Х		Х	Х			
Cornea X <td>Cardiac Tissue - non-valved</td> <td></td> <td>Х</td> <td>Х</td> <td></td> <td>Х</td> <td></td> <td></td> <td>Х</td> <td></td> <td></td> <td></td>	Cardiac Tissue - non-valved		Х	Х		Х			Х			
Dura Mater Dur	Cartilage		Х	Х		Х		Х	Х			
Embryo Image: Control of the control of t	Cornea		Х	Х		Х			Х			
Fascia	Dura Mater											
Heart Valve X <th< td=""><td>Embryo</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	Embryo											
HPC Apheresis Image: Cord Blood <	Fascia		Х	Х		Х		Х	Х			
HPC Cord Blood Image: Cord Blood	Heart Valve		Х	Х		Х			Х			
Ligament X<	HPC Apheresis											
Nerve Tissue Image: Company of the Compan	HPC Cord Blood											
Oocyte Courain Tissue Image: Courain Tissue in Courain Tissue i	Ligament		Х	Х		Х		Х	Х			
Ovarian Tissue Image: Control of the Collision of t	Nerve Tissue											
Pancreatic Islet Cells - autologous Image: Cells - autologous of the cells of the cells - autologous of the cells of the	Oocyte											
Parathyroid Image: Control of the control	Ovarian Tissue											
Pericardium X <th< td=""><td>Pancreatic Islet Cells - autologous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	Pancreatic Islet Cells - autologous											
Peripheral Blood Mononuclear Cells Image: Cell Series of	Parathyroid											
Peritoneal Membrane Image: Control of the	Pericardium		Х	Х		Х		Х	Х			
Sclera X <td>Peripheral Blood Mononuclear Cells</td> <td></td>	Peripheral Blood Mononuclear Cells											
Semen X <td>Peritoneal Membrane</td> <td></td>	Peritoneal Membrane											
Skin X	Sclera		Х	Х		Х			Х			
	Semen											
Tendon X X X X X X	Skin		Х	Х		Х		Х	Х			
	Tendon		Х	Х		Х		Х	Х			
Testicular Tissue	Testicular Tissue											
Tooth Pulp	Tooth Pulp											
Umbilical Cord Tissue	Umbilical Cord Tissue											

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3003103596 Legal Name: Indiana Organ Procurement Organization dba Indiana Donor Network